510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Abbott Vascular
Submitter's Address:	3200 Lakeside Drive, Santa Clara, CA 95054
Telephone:	951-914-3311
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Contact Person:	Nadine Smith
Date Prepared:	July 22, 2009
Device Trade Name:	Fox sv PTA Catheter
Device Common Name:	PTA Catheter
Device Classification Name:	Catheter
Device Classification No.:	21 CFR 870.1250
Device Classification:	Class II
Device Product Code:	LIT

Summary of Substantial Equivalence

The Fox sv PTA Catheter subject device is substantially equivalent to the predicate devices, Fox sv PTA Catheter and Fox Cross PTA Catheter, as demonstrated by the results of the *in vitro* bench tests, analyses and biocompatibility data.

Device Description

The Fox sv PTA Catheter is a standard over-the-wire PTA catheter. The double lumen catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon and is accessed via the side leg port. The balloon material expands to a known diameter at specific pressure. The second lumen, starting at the straight entry port, allows access to the distal tip of the catheter for guide wire insertion. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The balloon material expands to a known diameter at specific pressures.

Intended Use

The intended use for the device has not changed as a result of the modification.

> The Fox sv PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries.
>
> This catheter is not intended for the expansion or delivery of stents.

Summary of Technological Characteristics Compared to Predicate Device

The subject Fox sv PTA Catheter (line extension) is identical in technological characteristics to the Fox sv PTA Catheter, with respect to product code, classification section, classification name, intended use, catheter lengths, introducer sheath size, and guide wire compatibility. The subject PTA Catheter (line extension) is also substantially equivalent to the FoxCross PTA catheter with similar balloon diameters of 5.0 mm and 6.0 mm devices with balloon lengths of 20mm, 40 mm, 60 mm, 80 mm, 100mm and 120 mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 2 7 2009

Abbott Vascular
c/o Ms. Nadine Smith
Regulatory Affairs
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K092286
Trade/Device Name: Fox sv PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: July 27, 2009
Received: July 29, 2009

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known) K092286

Device Name Fox sv PTA Catheter

Indications for Use The Fox sv PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries.

This catheter is not intended for the expansion or delivery of stents.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. McNamara

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092286